## REMARKS

Claims 7-22 and 24-29 are pending in the application. Claims 1-6 and 23 are cancelled, and claims 7-15, 21, 22 and 24-29 are withdrawn without prejudice to or disclaimer of the subject matter contained therein. Support for the amendment to claim 16 can be found throughout the specification. This amendment is not believed to add new matter, and its entry is respectfully requested.

### *I. Specification Informalities*

Applicants have updated the Cross Reference to Related Applications section with the appropriate patent numbers.

### *II. Rejections Under 35 U.S.C. § 112, 1st ¶*

Claims 16-20 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the enablement requirement. Office Action, page 3. Solely to advance prosecution and not in acquiescence to the rejection, Applicants have amended claim 16. Applicants request that the Examiner reconsider and withdraw this rejection, which is now believed to be moot.

### *III. Rejections Under 35 U.S.C. §112, 2nd ¶*

Claims 16-20 are rejected under 35 U.S.C. §112, 2nd paragraph for allegedly being indefinite. Office Action, page 6. Solely to advance prosecution and not in acquiescence to the rejection, Applicants have amended claim 16. Applicants request that the Examiner reconsider and withdraw this rejection, which is now believed to be moot.

### *IV. Rejections Under 35 U.S.C. §102*

Claims 16-18 and 20 are rejected under 35 U.S.C. §102(b) for allegedly being anticipated by Karkhanis *et al.*, *Infection and Immunity 59*: 983-989 (1991) (herein, "Karkhanis *et al.*). Office Action, page 7. Applicants traverse this rejection.

### *A. Karkhanis et al.-Based Rejections Were Overcome in the Parent Application*

Applicants respectfully remind the Examiner that the Karkhanis *et al.* publication was previously cited by the Examiner in U.S. 09/749,233 (filed December 27, 2000, now US 6,680,061), the parent of the captioned application. The reasoning for the rejection in the parent '233 application is substantially identical to the present rejection, and is provided for the Examiner's convenience as Exhibit A. *See* pages 7-8. In the parent '233 application, Applicants traversed this rejection on multiple grounds, all of which reasons and arguments are fully incorporated herein. Ultimately, the Examiner agreed with Applicants and provided reasons for allowance of the '233 application over the Karkhanis *et al.* publication. The Examiner's reasons for allowing the '233 application over the Karkhanis *et al.* publication are provided herewith for the Examiner's convenience as Exhibit B. *See* pages 2-3.

Because the teachings of Karkhanis *et al.* have not changed, and because Applicants' claims include limitations that the Examiner has acknowledged not to be disclosed by Karkhanis *et al.,* Applicants respectfully assert that the rejection of the claims under 35 U.S.C. §102(b) in light of Karkhanis *et al.* is mistaken. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

### *B. Karkhanis et al.'s 26 kDa Sporulated Oocyst Antigen (SOA) Protein Is Not the Same as SEQ ID NO.: 3*

Applicants believe that the above comments in § ***IV.A.*** should be sufficient to remove the rejection based on Karkhanis *et al.* For further clarification, however, Applicants provide herewith additional information demonstrating that Karkhanis *et al.*'s 26 kDa sporulated oocyst antigen (SOA) protein is not the same as Applicants' SEQ ID NO.: 3.

The 26 kDa protein of Karkhanis *et al.* is the major protein of sporulated oocysts, and is not observed in sporozoite extracts. *See* Karkhanis *et al.,* "Sproozoite extract" and "Western blot" on page 987, and figure 12. Moreover, SEQ ID NO.:3 of Applicants' claimed invention is derived from sporozoites, a life stage of the parasite that is essentially different from sporulated oocysts with different antigenic proteins being expressed.

Moreover, Karkhanis *et al.*'s 26 KDa protein was extracted with Zwittergent 3-10 (or, Sulfobetaine 3-10), a bi-polar detergent used routinely for isolation of bipolar membrane proteins. *See* Karkhanis *et al.*, "Preparation of sporulated oocyst antigen (SOA)," page 983. Consequently, Karkhanis *et al.*'s 26 kDa peptide is a *hydrophobic* protein. In contrast, SEQ ID NO.:3 of Applicants' claimed invention is a *hydrophilic* protein.

### C. *Karkhanis et al.'s 22 kDa Sporozoite Protein Is Not the Same as SEQ ID NO.: 3*

Applicants believe that the above comments in § ***IV.A.*** should be sufficient to remove the rejection based on Karkhanis *et al.* For further clarification, however, Applicants provide herewith additional information demonstrating that Karkhanis *et al.*'s 22 kDa sporozoite protein is not the same as Applicants' SEQ ID NO.: 3.

Karkhanis *et al.* describe how a sporozoite fraction V contains the 22 kDa sporozoite polypeptide that reacts strongly with antisera to SOA fraction V. *See* page 988, right column, lines 22-27. Referring to the Karkhanis *et al.* publication, Crane, M. S. J. *et al., Infection and Immunity 59*: 1271-1277 (1991) (Exhibit C) discuss SO7', a cDNA clone that encodes an "extremely efficacious" antigen identified in screening experiments using SOA fraction V antisera[1]. *See* Exhibit C, page 1271, right column, first full paragraph. Crane *et al.* refer to Liberator, P. *et al., Nucleic Acids Res. 17*: 7104 (1989) (Exhibit D) to provide the SO7' nucleotide and encoded peptide sequence. *See* Exhibit C, page 1271, last two lines in the right column.[2] Exhibit D clearly demonstrates that SO7 encodes a 22.4 kDa sporozoite peptide *that is entirely different from Applicants' claimed SEQ ID NO.: 3*. Hence, the 22 kDa sporozoite peptide discussed in Karkhanis *et al.* does not anticipate Applicants' claims.

Moreover, Karkhanis *et al.*'s 22 KDa protein was extracted with Zwittergent 3-10 (or, Sulfobetaine 3-10), a bi-polar detergent used routinely for isolation of bipolar membrane proteins. *See* Karkhanis *et al.*, "Preparation of sporulated oocyst antigen (SOA)" and "Preparation of sporozoite antigens," page 983. Consequently, Karkhanis *et al.*'s 22 kDa peptide

[1] Crane *et al.* identifies Karkhanis *et al.* as citation #23.
[2] Crane *et al.* identifies Liberator *et al.* as citation #28.

is a *hydrophobic* protein. In contrast, SEQ ID NO.:3 of Applicants' claimed invention is a *hydrophilic* protein.

***D. Summary of Arguments***

In summary, Applicants assert that

- The Examiner has already acknowledged that SEQ ID NO.: 3 (as claimed by Applicants) is not anticipated by Karkhanis *et al.*

- Karkhanis *et al.*'s 26 kDa protein is derived from a different stage of the parasite (i.e., sporulated oocysts), using a detergent that selects for *hydrophobic* proteins. It is therefore virtually impossible that this 26 kDa protein would have the same characteristics (or be the same) as Applicants' claimed *hydrophilic* SEQ ID NO.: 3.

- Karkhanis *et al.*'s 22 kDa protein has an amino acid sequence entirely different from SEQ ID NO.:3; and like the 26 kDa protein, is extracted using a detergent that selects for *hydrophobic* proteins (and not for the claimed hydrophilic protein).

Hence, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 16-18 and 20 under 35 U.S.C. § 102(b), as Karkhanis *et al.* fail to anticipate Applicants' claimed invention.